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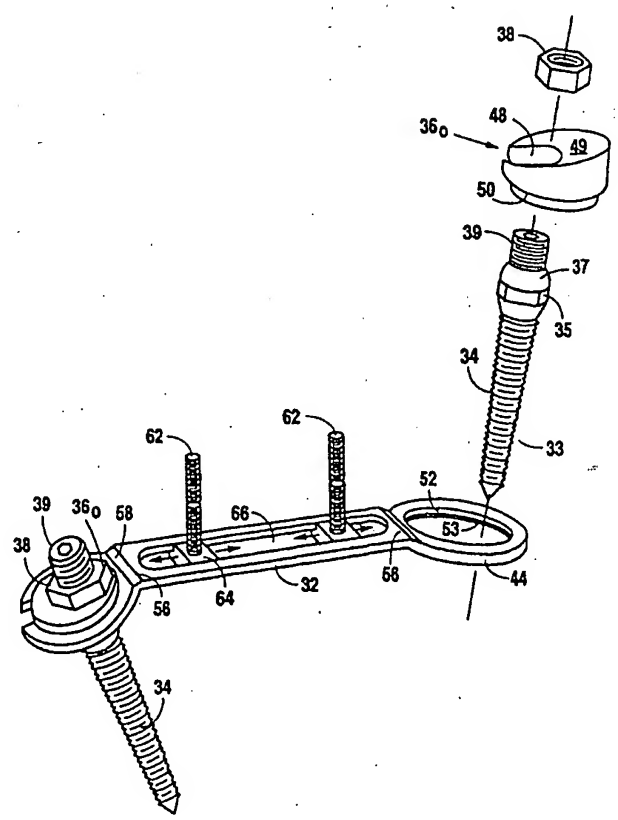
(54) Title: MULTI-AXIS CONNECTIONS BETWEEN SPINAL STABILIZERS AND SCREWS

(57) Abstract

A multi-axis correction washer for use with a spinal stabilizer for internal spinal fixation. The bodies of the washer are provided in cylindrical and wedge-shaped cylindrical configurations with a passage in the center of the longitudinal axis of the cylinder and/or offset from the center axis of the cylindrical washer and a shoulder or other structure for rotatably engaging a hole in a spinal implant. The spinal implant can be a plate and screw-type, ladder-type, or monorail-type spinal fixation system. The washer is rotated to provide an infinite range of angles and screw placements relative to the central axis of the spinal column for maximum flexibility of installation and to effectively transfer the load on the spinal column to the implant, all while maintaining an angle of approximately 90° between the head of the screw and/or nut and the washer which engages the implant.



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MULTI-AXIS CONNECTIONS BETWEEN SPINAL STABILIZERS AND SCREWS

The present invention relates to apparatus and methods of multi-axis internal spinal fixation. In more detail, the present invention relates to a connection for use in an internal spinal fixation system, and a method of stabilizing, or fixing, the spine for use with either bilateral rods or plates (such as the Steffee/variable screw placement system) or a central rod and plurality of cross-bars or plates (such as the so-called Tacoma Monorail System), utilizing wedge-shaped and/or flat washers having off-set and/or centered openings therein to provide multiple axes for the pedicle screws used to fix the rods, cross-bars, and/or plates to the vertebrae of the patient, thereby effectively transferring the load from the spinal column to the spinal stabilizer.

There are many systems available for internal fixation of the spine. Such systems are described in the patent literature (*see*, for instance, U.S. Patent Nos. 4,696,290, 5,092,866, and 5,129,899) and the scientific literature (*see*, for instance, D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine (Philadelphia: Nanley & Belfus, Inc.) 1992 and H.S. An and J.M. Cotler (Eds.), Spinal Instrumentation (Baltimore: Williams & Wilkins) 1992), and are available from such vendors as AcroMed, Smith & Nephew, MOSS® Miami, Osteonics, Sofamor Danek, and others.

A problem with all such systems, however, is the connection between the screws used to affix the system to the pedicle and the rods, cross-bars, and/or plates of the system. As stated in J.M. Cotler, *et al.*, Principles, Indications, and Complications of Spinal Instrumentation: A Summary Chapter, *in* H.S. An and J. M. Cotler, Spinal Instrumentation pp. 435-456 (Baltimore: Williams & Wilkins) 1992, "[a] significant problem in pedicular screw fixation appears to be at the site of linkage between the screw and rod or plate."

It appears that the problems at the site of this linkage may result from the geometry of the connection between the screw and the rod or plate. This difficult geometry results from several factors, including the different angles and placement of the vertebrae and their relative sizes, the shape of the vertebrae and the spacing between vertebrae, the placement

of the screws, the lordosis of the spine, and the need to insert the screws into each vertebra at an angle. With regard to the angle of the pedicle screws, pedicle screws are angled inwardly and upwardly into the vertebra for maximum strength and, because the surfaces of the pedicles of each vertebrae are angled relative to each other, the screws rarely line up across the vertebral body into which they are screwed. Nor do they usually line up from one vertebra to the adjacent vertebra, even if the adjacent vertebrae are the same size and shape (which they generally are not). For a more complete discussion of the biomechanics of the bone-implant interface, reference is made to H.A. Pool and R.W. Gaines, Biomechanics of Transpedicular Screw Spinal Implant Systems, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 37-44 (Philadelphia: Nanley & Belfus, Inc.) 1992, M.R. Pinto, Complication of Pedicle Screw Fixation, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 45- 54 (Philadelphia: Nanley & Belfus, Inc.) 1992, and M.H. Krag, Vermont Spinal Fixator, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 121-145 (Philadelphia: Nanley & Belfus, Inc.) 1992, which references are incorporated herein in their entirety by these specific references thereto. Because the pedicle screws do not line up, the rod (or rods depending upon the particular stabilizer utilized) which runs along the longitudinal axis of the patient's spinal column, which provides the structural rigidity required to stabilize the spine, must either be bent to the location of each screw head or the stabilizer must be provided with adjustable structure which enables the head of the pedicle screw to be attached to the rod.

As a result of this difficulty, the literature includes comments such as the following statement in R.M. Puno and J.A. Byrd III, Transpedicular Screw/Rod Fixation Using the Puno-Winter-Byrd (PWB) System, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 83-106 (Philadelphia: Nanley & Belfus, Inc.) 1992:

> "Transpedicular fixation has been proved to be of value in the treatment of spinal disorders . . .. However, experience has shown that this method of instrumentation places great demand on the surgeon's skill because of the anatomic constraints related mainly to the anatomy and morphometry of the spinal pedicle."

Many of the above-listed systems, and many of the systems described in the literature, attempt to relieve this burden on the surgeon by providing angled screws (for instance, the AMSET® R-F reduction-fixation system), so-called polyaxial screws (for example, the MOSS® Miami system noted above), full-length, scalloped, open-slot plate design with an undersurface complementary to the shape of the screw head (the Sofamor Danek plate and screw system noted above for example) for optimal positioning of the screws and up to 15° medial-lateral and 30° craniocaudal angulation at the screw-plate interface, and infinitely variable couplers (the so-called Rogozinski spinal rod system for example) which are said to allow rotation through a 130° arc to allow screw placement within the pedicle with no requirement to align each screw with the screw in the adjacent vertebrae.

Although these prior systems address these problems, as evidenced by the fact that new systems are introduced by the same vendors which are already marketing the above-listed systems, no currently available system completely solves all the problems presented by the need for optimal screw placement, angulation of the screw, and effective load transfer from spinal column to implant. An ideal system would (a) accomodate optimal screw placement, height, and angulation, (b) accomodate different sizes and shapes of vertebrae, (c) minimize (or not require) bending or other fabrication during surgery, (d) maintain an angle of approximately 90° at the connection between the screw head and the plate or cross-bar to which the screw is attached for effective load transfer from spinal column to implant and to minimize the likelihood of slippage and/or gross failure, and (e) be strong enough to provide lasting and rigid fixation of the spine. Those skilled in the art will recognize that this list is not exhaustive, but is instead intended to illustrate some of the desirable characteristics of an ideal internal fixation system. Other design criteria are also important, and some practicioners may consider some criteria so important that they might not even list others.

So far as is known, none of the above-listed internal fixation systems meets these criteria in every patient. The disadvantages and limitations of currently available systems are made clear from reports in the literature of failure rates (failure of the device, not such complications as infection, phlebitis, seroma, neurologic deficit, etc.) as high as 25% (*see* R. Roy-Camille, *et al.*, 203 Clin. Orthop. 7 (1986)), 11% (*see*, S.F. Heim and E.R. Luque, Danek Plaste and Screw System, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the

Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 201-234 (Philadelphia: Nanley & Belfus, Inc.) 1992), 8% (*see*, R.M. Puno and J.A. Byrd III, Transpedicular Screw/Rod Fixation Using the Puno/Winter/Byrd (PWB) System, *supra*), and 2-7% D.M. Arnold and L.L. Wiltse, The Wiltse System of Internal Fixation for the Lumbar Spine, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 55-82 (Philadelphia: Nanley & Belfus, Inc.),1992.

The currently available systems have other limitations. By way of example, so far as is known, no currently available surgically implanted system can predictably treat rotoscoliosis. Further, no currently available system is conveniently used in multiple level surgery. Multiple level surgery is a challenge for the surgeon because of the need to align the pedicle screws in multiple vertebrae while working under the heavy muscles of the back.

There is therefore a need for improvement of such systems, and it is this improvement to which the present invention is directed. In particular, it is an object of the present invention to improve the screw-plate interface in those systems in which the screw is angled and/or spaced at varying intervals. Another object of the present invention is to provide flexibility of placement, angulation, spacing, and screw height for accomodating the pedicle screws of such systems. Another object of the present invention is to provide a system which is universal in the sense that, although comprised of relatively few parts, it works with pedicle screws and laminar hooks, thereby providing even more flexibility and ease of use. Another object of the present invention is to provide an internal spinal fixation system which avoids surgery under the heavy muscles of the back so that the surgery is simplified and there is more room for fusion of adjacent vertebrae in the lateral gutter. Other objects, and the advantages, of the present invention will be made clear to those skilled in the art by the following description of the preferred embodiments thereof.

These objects, and other objects to be made clear by the following detailed description of the invention, are met by providing a connection between a spinal stabilizer and a pedicle screw comprising a washer defining means for engaging a spinal stabilizer, means on the spinal stabilizer for engaging the washer, the engaging means on the washer and the engaging means of the spinal stabilizer cooperating to engage each other at a plurality of points within a common plane with the washer in any one of a plurality of

relative rotational positions about an axis substantially perpendicular to the common plane relative to the spinal stabilizer. The washer defines a bearing surface and a passage extending through the washer, the pedicle screw extending through the passage and bearing against the bearing surface when the spinal stabilizer is affixed to a vertebral body. In one embodiment, the engaging means on the washer comprises means for resting on and rotatably engaging in the spinal stabilizer adjacent the periphery of an aperture in the spinal stabilizer so that the washer is capable of being rotated in the aperture to provide an infinite variety of angles and pedicle screw placements while maintaining an optimal interface between the head of the screw and the washer so as to effectively transfer the load from the spinal column to the spinal stabilizer.

The invention also contemplates a spinal stabilizer including such a connection. The spinal stabilizer of the present invention comprises an elongate member adapted to be affixed to a vertebra and defining a planar aperture. A washer is provided with engagement means adapted to engage the elongate member adjacent the periphery of the aperture at any one of a plurality of relative rotational positions between the washer and the elongate member about a notional rotational axis which extends through the aperture, the washer having a passage therethrough, one end of the passage communicating with the plane of the aperture and the other end of the passage being located at a bearing surface formed on the washer. A pedicle screw engages the bearing surface and extends through the passage and the aperture to engage the vertebral body of the vertebra, the axis of the passage intersecting the plane of the aperture at a first angle and the bearing surface at a second angle, at least one of the angles being acute, the plane of the aperture being inclined relative to the bearing surface so that the angle of inclination of the screw extending through the passage is adjusted in dependence upon the relative rotational position between the washer and the elongate member.

In another aspect, the present invention contemplates a novel washer for use in connection with an internal spinal stabilizer which comprises a wedge-shaped, cylindrical body with a passage through the body which is offset from the center of the longitudinal axis of the washer. The passage receives a screw for affixing an internal spinal stabilizer to the vertebral body of a patient. Means is formed on said body for rotatably engaging the

spinal stabilizer to allow the body to rotate around the 360° of the hole to provide infinite variability in the angle and location of the interface between the screw and the plate.

In another aspect, the present invention comprises a washer for use with an internal spinal stabilizer comprising a body defining means adapted to engage cooperating engagement means on a spinal stabilizer, the engagement means on the washer being adapted to engage the cooperating engagement means on the stabilizer at a plurality of points within a common plane and with the washer in any one of a plurality of relative rotational positions about an axis substantially perpendicular to the common plane relative to the stabilizer, a passage extending through the washer and defining an axis that intersects the common plane at a first predetermined angle at one end of the passage and a bearing surface, the axis of the passage intersecting the plane of the bearing surface at a second predetermined angle, at least one of the first or second predetermined angles being an acute angle.

In another aspect, the washer comprises a body defining first engagement means adapted to engage cooperating engagement means provided on the internal spinal stabilizer with the washer being rotated to any one of a plurality of positions about an axis substantially perpendicular to a first plane defined by points of contact between the first engagement means and the second engagement means, the washer also defining a bearing surface that is inclined relative to the first plane, there being a passage extending through the washer and defining an axis, the axis of the passage intersecting the first plane at a first predetermined angle and the bearing surface at a second predetermined angle, at least one of the predetermined angles being acute.

The present invention also provides a method of affixing a spinal stabilizer to the vertebra of a patient, the stabilizer comprising a washer having an off-center passage therethrough, a cross-bar, and a screw, comprising the steps of engaging the cross-bar with the washer, driving the screw into the vertebral body through the passage in the washer, and changing the angle of the screw relative to the vertebral body to which the cross-bar is affixed by rotating the washer relative to the cross-bar.

In a second embodiment of the method of affixing a spinal stabilizer to the vertebra of a patient, the spinal stabilizer comprises a washer having a cylindrical body with one end angled with respect to the side walls of the cylinder and a longitudinal passage

therethrough, a cross-bar, and a screw, and the method comprises the steps of engaging the cross-bar with the washer, driving the screw into the vertebral body through the passage in the washer, and changing the angle of the screw relative to the vertebral body to which the cross-bar is affixed by rotating the washer relative to the cross-bar.

It is also an aspect of the invention to provide a spinal stabilizer for affixing to the vertebral body of a patient comprising first and second elongate members attached to each other at an angle of approximately 90°, the second elongate member being rotatable about its longitudinal axis relative to the first elongate member, a washer, and means on the second elongate member for engaging the washer in any one of a plurality of relative rotational positions at a plurality of points within a common plane about an axis substantially perpendicular to the common plane.

Referring now to the Figure 1 of the drawings, there is shown a partially schematic, dorsal view of a portion of the human spinal column having a first embodiment of a spinal stabilizer constructed in accordance with the teachings of the present invention surgically affixed thereto.

Figure 2 is a lateral view of the human spinal column having the spinal stabilizer of Fig. 1 affixed thereto and showing the spinal column in phantom lines to show the positions of the pedicle screws used to affix the spinal stabilizer to the spinal column.

Figure 3 is a top plan view of a lumbar vertebra having the spinal stabilizer of Figs. 1 and 2 affixed thereto and showing the vertebra in phantom lines to show the positions of the pedicle screws used to affix the spinal stabilizer to the spinal column.

Figure 4 is top, perspective view of a first embodiment of a washer constructed in accordance with the teachings of the present invention.

Figure 5 is a top, perspective view of a second embodiment of a washer constructed in accordance with the teachings of the present invention.

Figure 6 is a bottom, perspective view of a third embodiment of a washer constructed in accordance with the teachings of the present invention.

Figure 7 is a side elevational view of the washer of Fig. 6.

Figure 8 is a bottom, perspective view of a fourth embodiment of a washer constructed in accordance with the teachings of the present invention.

Figure 9 is a side elevational view of the washer of Fig. 8.

Figure 10 is a perspective view of a second embodiment of the washer of Fig. 8.

Figure 11 is a side elevational view of the washer of Fig. 10.

Figure 12 is a partially exploded, perspective view of a portion of a second embodiment of a spinal stabilizer constructed in accordance with the teachings of the present invention.

Figure 13 is a side elevational view of a portion of the cross-bar of the spinal stabilizer of Fig. 12.

Figure 14 is a partially schematic, dorsal view of a portion of the human spinal column having a third embodiment of a spinal stabilizer constructed in accordance with the teachings of the present invention surgically affixed thereto.

Figure 15 is a perspective view of the cross-bar of the spinal stabilizer of Fig. 14.

Figure 16 is a dorsal view of a single lumbar vertebrae having a fourth embodiment of a cross-bar constructed in accordance with the teachings of the present invention affixed thereto for use in connection with the spinal stabilizer of Fig. 14.

Figure 17 is an enlarged, exploded perspective view of the cross-bar of Fig. 16.

Figure 18 is a detailed, side elevational view of a portion of the cross-bar of Fig. 16.

Figure 19 is a partially schematic, dorsal view of a portion of a human spinal column having a fifth embodiment of a spinal stabilizer constructed in accordance with the present invention affixed thereto.

Figure 20 is a perspective view of a portion of the spinal stabilizer of Fig. 19.

Figure 21 is a perspective, detailed view of a portion of the spinal stabilizer of Fig. 19.

Figure 22 is also a perspective, detailed view of a portion of the spinal stabilizer of Fig. 19.

Figure 23 is a partially schematic, dorsal view of a portion of a human spinal column having a sixth embodiment of a spinal stabilizer constructed in accordance with the present invention affixed thereto.

Figure 24 is a perspective, partially exploded view of a portion of the spinal stabilizer of Fig. 23.

Figure 25 is a bottom perspective view of a washer for use in connection with the spinal stabilizer of Fig. 24.

Figure 26 is a side elevational view of the washer of Fig. 25.

Figure 27 is a sectional view through a portion of the cross-bar of another embodiment of the present invention.

Figure 28 is a sectional view through a portion of the cross-bar of yet another embodiment of the present invention.

Referring now to the figures, a first embodiment of a spinal stabilizer constructed in accordance with the present invention is shown affixed to the spinal column in Figs. 1 and 2. This first embodiment, indicated generally at reference numeral 20, is comprised of two elongate members, or rods 22 oriented along the longitudinal axis of the spinal column 24 on either side of the spinous processes 26 of lumbar vertebrae L3-L5 and the first sacral vertebrae S1. Rods 22 are connected at the level of each vertebrae S1, L3-L5 by nut and screw 28 and 30 to cross-bar, or plate, 32. The screws 30 are preferably of a type known in the art in which the portion of the screw threads projecting through nut 28 is broken off so as not to project any further from the nut 28 than needed. Each cross-bar/plate 32 is affixed to the corresponding vertebrae by a pedicle screw 34, washer 36, and nut 38, screws 34 being anchored in the pedicle 40 (see Fig. 3) of each vertebrae. Screws 34, shown in more detail in Fig. 12, are also of a type known in the art in which the bottom portion 33 is provided with threads for anchoring into the vertebrae, a head 35 with a rounded, or hemispherical upper surface 37, and an upper threaded portion 39 for threadably receiving the nut 38 and the portion of the threads projecting through nut 38 is broken off so as not to project any further through nut 38 than needed. A screw of this type is shown, for instance, in U.S. Patent No. 5,129,899, which patent is incorporated herein in its entirety by this specific reference thereto.

As noted above, the need for secure anchorage of the screws 34 in the vertebrae, the lordosis of the spine and corresponding curve in rods 22 (best shown in Fig. 2), inward angle of the screws 34 (best shown in Fig. 3), different sizes, spacing, and shapes of the vertebral bodies 42, and many other factors (including the particular pathology which the spinal fixation system is intended to address), require that almost every screw 34 must be oriented at a unique angle relative to rods 22. To illustrate, in Figs. 1 - 3, it can be seen that each screw is angled in three axes of a three-dimensional coordinate system (not shown) having its origin on the center axis of the spinal column 24. If the Y coordinate of the

coordinate system is coincident with the center of the longitudinal axis of the spinal column 24 (such that +Y is anterior and -Y is posterior), the X coordinate is the lateral dimension, and the Z coordinate is orthogonal to the plane of the paper in Fig. 1 (such that +Z is ventral and -Z is dorsal), it can be seen in Fig. 2 that the positions of the tips of the screws 34 are defined by Y and Z coordinates. Reference to Fig. 3 (in which the Y coordinate of the hypothetical coordinate system runs in and out of the plane of the paper) illustrates that the positions of the tips of the same screws are also defined by an X coordinate.

Also in Fig. 3, it can be seen that the ends 44 of cross-bar 32 are angled downwardly, or ventrally (relative to the body of the patient), to accommodate the round shape of the body 42 of the vertebrae L4 to which the cross-bar 32 is affixed by screws 34. Although the cross-bar 32 need not be shaped in this fashion, this bend at the ends 44 of cross-bar 32 serves several advantages other than accommodating the shape of the vertebral body (for instance, reducing the height of the stabilizer in the direction of the Z coordinate of the three-dimensional coordinate system described above) and is therefore particularly adapted for use in the spinal fixation system of the present invention. However, the downward bends at the ends 44 also introduces yet another angle into the interface between the screw 34 and the cross-bar 32. As a result of the angle of the screw 34 and the bend at the end 44 of cross-bar 32, the longitudinal axis of screw 34 is unlikely to be perpendicular to cross-bar 32 at the connection between the screw 34 and cross-bar 32, and therefore unlikely to optimally transfer load from the spinal column 24 to the spinal stabilizer 20.

Figs. 4-9 show a plurality of washers 36 constructed in accordance with the teachings of the present invention shaped and/or configured to provide optimal load transfer from the spinal column 24 to the spinal stabilizer 20 through pedicle screw 34. The washers 36_c and 36_o shown in Figs. 4 and 5, respectively, are comprised of a cylindrical body 46 having a longitudinal passage 48 therethrough for receiving the screw 34 for affixing the spinal stabilizer 20 to the vertebral body 42. The passage 48 through the body 46 of washer 36_c is centered on the longitudinal axis (represented by the phantom line 37, 47 in Fig. 4) of washer 36_c and the axis 47 of the passage 48 in the body 46 of washer 36_o (Fig. 5) is offset from the longitudinal axis 37 of the washer 36_o for a purpose to be described below. Each of the washers 36_c and 36_o is also provided with means formed on

the body 46 for rotatably engaging the spinal stabilizer 20. This engagement means takes several forms; in the embodiment shown in Figs. 4-9, the stabilizer engaging means comprises a shoulder 50 formed on the body 46 of the washers 36_c and 36_o which rests on the cross-bar 32 (not shown) adjacent the periphery of the aperture 52 formed in the ends 44 of cross-bar 32 when the washer 36_c or 36_o is assembled to the cross-bar 32 in the manner described below.

Those skilled in the art will recognize that the stabilizer engaging means need not be comprised of the shoulder 50. In a second embodiment (not shown), the stabilizer engaging means takes the form of three or more radially outwardly extending projections on the surface of the walls of the cylindrical body (the "O.D." of the body) which, when the body is inserted through the aperture 52 in the cross-bar 32, create an interference with the margin of aperture 52 so that the washer effectively sits in the aperture 52 with the projections on the O.D. of the body acting as a spider engaging the periphery of aperture 52 to support the washer in the aperture 52. Alternatively, and particularly in the case of the washers shown in Figs. 6-10 described below, the O.D. of the body 46 of washer 36 is provided with a groove and the washer is inserted with the angled top surface 49 (see below) up from beneath the aperture 52 in cross-bar 32 and rotated so that the groove engages and interacts with the periphery of the aperture 52 so as to limit the travel of the washer through the aperture 52. In another embodiment, the stabilizer engaging means takes the form of a plurality of projections projecting radially inwardly from the periphery of the aperture in the cross-bar for engaging a shoulder or slot formed on the O.D. of the body of the washer. In yet another embodiment, the washers are comprised of a resilient material such as a medical grade polymeric material which are provided with a groove formed on the O.D. thereof which is press-fit into the aperture 52 in cross-bar 32.

The engaging means need not be formed on just the washer to fall within the scope of the present invention. In the embodiment shown in Figs. 24-28, the aperture 52 is provided with either a raised boss 110 for engaging either a recess 112 in the bottom surface of the washer $36_o'$ shown in Figs. 25-26 or a shoulder 114 (see the left side of Fig. 24) for receiving the body of a washer $36_o''$ with straight sides as shown in Fig. 27. In another embodiment shown in Fig. 28, the aperture 52 of the cross-bar 32 is provided with a hollowed out edge 116 for engaging the rounded bottom surface 118 of the washer $36_o'''$

shown in Fig. 28. Alternatively, the inside edges of the aperture 52 are beveled and the bottom edge of the washer is provided with a complimentary bevel for engaging the washer. All such embodiments, and others functioning to allow the washer to engage the aperture in the cross-bar at a plurality of points within a common plane in any one of a plurality of rotational positions relative to the cross-bar of the spinal stabilizer which may be developed by those skilled in the art who have the benefit of this disclosure, are considered equivalent to the structure disclosed herein and are therefore considered to be constructed in accordance with the present invention.

Other embodiments of the washer 36 of the present invention are shown in Figs. 6-7 and 8-9. Again, the axis 47 of the passage 48 in the cylindrical body 46 of washer 36_c shown in Figs. 6 and 7 is centered on the longitudinal axis (represented by the phantom line 37 in Fig. 6) of washer 36_c and, when viewed from the end 49, the longitudinal passage 48 in the cylindrical body 46 of washer 36_o in Figs. 8 and 9 is offset from the center of the longitudinal axis (represented by the phantom line 37 in Fig. 8) of washer 36_o. Unlike the washers 36 shown in Figs. 4 and 5, the end 49 of each of the washers shown in Figs. 6-9 is angled at an angle other than 90° relative to the side walls of the cylindrically-shaped body 46, giving the body 46 a wedge shape. As a result of the angled end 49 of body 46, the axis 47 of the passage 48 through washer 36_o shown in Figs. 8-9 is not parallel to the longitudinal axis 37 of the body 46.

Like the washers 36 shown in Figs. 4-5, the washers 36 shown in Figs. 6-9 are provided with means for rotatably engaging an aperture in the spinal stabilizer 20 at any one of a plurality of relative rotational positions about a notional axis which extends through the aperture. As described above, in the embodiment shown, the stabilizer engaging means takes the form of a shoulder 50 formed on the body 46 of washers 36_c and 36_o which rests on the surface of cross-bar 32 adjacent the periphery of the aperture 52 formed in the ends 44 of cross-bar 32 when the washer 36_c or 36_o is assembled to the cross-bar 32 (the manner in which the shoulder functions is described below). Those skilled in the art will recognize from this disclosure that other shoulder engaging means such as are described above may be provided on the washers 36 to accomplish the intended function of allowing the washer 36 to rotate in engagement with cross-bar 32.

The bodies 46 of the washers 36 are described as being cylindrical to provide a basis for referring to the longitudinal axis of the washer 36 even though it will be recognized that the height of the right angle cylinder defined by the washers of Figs. 4 and 5 is minimal since the washers shown in Figs. 4 and 5 are accurately described as "flat washers." However, as set out above, one end 49 (defining the bearing surface against which the screw 34 is tightened to affix the spinal stabilizer to the vertebra) of the bodies 46 of the washers 36 shown in Figs. 6-9 is angled relative to the side walls of the cylindrically-shaped body 46 of washer 36. In the embodiments shown in Figs. 4 and 5, the end 49 is angled at an angle of approximately 90° such that the washers shown in those figures are flat, but the end 49 of the bodies 46 of the washers 36 shown in Figs. 6-9 is angled relative to the side walls at an angle other than 90° such that the bodies 46 of washers 36 shown in those figures have a substantial vertical dimension and are wedge-shaped rather than flat. A variety of angles may be utilized to advantage, but angles (relative to the side walls of the cylindrically-shaped body 46) ranging from about 7.5° to about 30° have generally proven to be adequate to provide a full range of adjustability. It will also be recognized by those skilled in the art that although the washer of the present invention is defined as being cylindrical, the body of the washer need not be cylindrical. All that is required is that the washer be capable of being rotated to a [lurality of positions relative to the cross-bar of the spinal stabilizer. A plurality of positions can be obtained with, for instance, a square (or octagonal or triangular) aperture in the cross-bar and a similarly-shaped washer since the washer could then be placed in as many as four (or eight or three) different relative positions about the notional axis which is substantially perpendicular to the plane of the aperture. All such embodiments are contemplated by the use of the word "cylindrical" in describing the washer of the present invention.

Referring now to Figs. 10 and 11, an alternative embodiment of the washer of the present invention is shown. The washer 36 shown in Figs. 11 and 12 is similar to the washers shown in Figs. 6-9, but is provided with a concave upper surface 49 for interaction with a nut 38 (not shown) having a convex lower surface. When tightened onto the pedicle screw 34, the concave upper surface 49 provides an even greater range of angles and adjustability of placement of the screw 34 relative to the central axis of the spinal column. Because the surface 49 is the end surface of the body 46 comprising washer 36 against

which the pedicle screw 34 bears, it is referred to herein as the bearing surface 49 of washer 36.

As best shown in Figs. 3 and 12, washers 36 rotatably engage cross-bar 32 at the ends 44. As described above, rotatable engagement is accomplished by resting the shoulders 50 of washers 36 comprising the preferred stabilizer engaging means on the margins of the apertures 52 at the ends of cross-bars 32. During the surgical procedure, the surgeon selects either

a flat washer with a longitudinal passage coincident with the center of the longitudinal axis of the washer (Fig. 4),

a flat washer with a passage offset from the center of the longitudinal axis of the washer (Fig. 5),

a wedge-shaped washer with a passage coincident with the center of the longitudinal axis of the washer (Figs. 6-7), or

a wedge-shaped washer with a passage offset from the center of the longitudinal axis of the washer (Figs. 8-9),

and then rotates the body 46 of the washer 36 selected in the aperture 52 to provide infinite adjustability of the linkage between the cross-bar 32 and screw 34, regardless of the angle and position of the screws 34 in the pedicle 40 of each vertebrae and regardless of the shape, size, or pathology of the vertebrae and/or pedicle. For even more adjustability, a washer with a concave bearing surface 49 or a rounded bottom (for engagement of an aperture having a hollowed-out margin as shown in Fig. 28) is utilized. The washer selected is preferably the washer which, by its shape and ability to be rotated, locates the passage therethrough in the proper position for receiving the screw 34 while maintaining an angle of approximately 90° between the longitudinal axis of the screw 34 and the bearing surface 49 of the washer against which the nut 38 bears when tightened to effectively transfer load from the spinal column 24 to the implant 20. It will be noted that when the screw 34 engages the bearing surface 49 of washer 36 and extends through the passage 48 and the aperture 52 to engage the vertebra, the axis 47 of passage 48 intersects the plane of the aperture at a first angle and, depending on whether the bearing surface 49 is inclined, or angled, the rotational position of the washer relative to the spinal stabilizer, may intersect

the bearing surface 49 at a second angle, but that at least one of the first or second angles must be an acute angle.

To facilitate assembly of the cross-bar 32 to the screws 34, one end 44 of cross-bar 32 may be provided with a gap or break 45 through which the portion of the screw 34 protruding from the pedicle is maneuvered. Also, because the angle between the underside of cross-bar 32 and the longitudinal axis of screw 34 is unlikely to be a 90° angle and/or the screw 34 may be positioned close to the inside margin of the aperture 52 in cross-bar 32, the upper surface 37 of the head 35 of screw 34 is rounded and the inside surface of the margin of the apertures 52 in cross-bar 32 is beveled as shown at reference numeral 53 in Fig. 13. In another embodiment (not shown), the head of screw 34 is sized so as to contact the margin of aperture 52 in cross-bar 32, the bevel 53 and complementary rounded upper surface 37 of the screw 34 helping to center the longitudinal axis of aperture 52 in cross-bar 32 on the longitudinal axis of screw 34.

Fig. 12 shows the interaction and adjustability of the spinal implant of the present invention by showing one screw 34 to which a nut 38 is tightened against the wedge-shaped washer 36_o of Figs. 8 and 9 with the washer 36_o having been rotated relative to cross-bar 32 in the common plane formed by the cooperating engaging means on the washer and the cross-bar 32 of the spinal stabilizer so that the screw 34 is angled anteriorally (with reference to the patient) while also being angled inwardly (relative to the central axis of the spinal column 24). A flat washer 36_o is shown on the other side of the cross-bar 32 which has been rotated so that the screw 34 is not centered in the aperture 52 of cross-bar 32 but the inward angle of the screw resulting from the downward bend at the ends 44 of cross-bar 32 is maintained. Cross-bar 32 is shown with an optional nipple 56 forming a stop surface 58 near the apertures 52 therethrough which acts, by engagement of the O.D. of the washer 36, to restrain any tendency of the washer 36 to move inwardly from the ends 44 of cross-bar while the nut 38 is being tightened against the washer 36 when in place in the aperture 52 in cross-bar 32.

Referring briefly again to Fig. 1, the portion of cross-bar 32 intermediate the ends 44 is provided with a plurality of nested slots 60 of a type known in the art (*see*, for instance, U.S. Patent No. 4,696,290 and the so-called VSP spinal fixation system described in J.W. Brantigan, et al., Posterior lumbar interbody fusion technique using the variable

screw placement spinal fixation system, *in* D.M. Arnold and J.E. Lonstein (Eds.), 6 State of the Art Reviews - Spine: Pedicle Fixation of the Lumbar Spine 201-234 (Philadelphia: Nanley & Belfus, Inc.) 1992, both references being hereby incorporated in their entirety by this specific reference thereto) for precise placement of the screws 30 securing the rods 22 to the cross-bars 32 along the longitudinal axis of cross-bar 32. The screws 30 for securing the rods 22 to the cross-bars 32 are of the above-described type known in the art in which the portion of the screw which extends above the top surface of the nut 28 is broken off after the nut is tightened.

By comparison to Fig. 1, it can be seen that in the embodiment shown in Fig. 12, the attachment between rods 22 and cross-bars 32 is accomplished by tightening nuts 28 to the posts 62 integrally mounted to the plate 64 which moves from side to side along the longitudinal axis of cross-bar 32 in the slot 66 formed therein. The plate 64 is comprised of a flat portion (not visible in Fig. 12 because of the perspective in the figure) which extends under the cross-bar and which is tightened against the underside of cross-bar 32 when the nut 28 is tightened against a rod 22 to prevent further side to side movement of the plate 64 and post 62. Before tightening the nut 28, the plate is moved by the surgeon to the position which allows precise alignment of the rod 22 with the cross-bar 32.

In the embodiment shown in Figs. 14-15, the rods 22 are of a type known in the art such as those available from MOSS® Miami (Cat. No. 1745-70, -72, and -74) which are attached to cross-bars 32 by U-shaped connectors 68 having threads 70 formed on the outside surfaces thereof. For purposes of convenience, the rods 22 may be referred to generically as first elongate members and the cross-bars 32 are referred to a second elongate members. Connectors 68 are integrally mounted to a plate 64 having a construction similar to that of the so-called axial connectors available from MOSS® Miami (Cat. No. 1745-61 and -62), e.g., two halves (not shown) with threaded posts and nuts for connecting the halves on the top and bottom of the cross-bar 32 to clamp the cross-bar 32 and prevent side to side movement of the plate 64 in the slot 66 in cross-bar 32 in which the plate 64 moves. Alternatively, the plate 64 is provided with a portion extending under cross-bar 32 which is tightened against the underside of cross-bar 32 when the nut 28 is tightened on connector 68 to resist further side to side movement. Those skilled in the art will recognize from this description of the connectors 68 and plates 64 that a similar

arrangement may be used in place of the nested slots 60 in the cross-bar 32 of the embodiment shown in Fig. 1 wherein the threaded posts 62 are replaced by connectors 68 for precise lateral placement of the point at which the rods 22 are attached to cross-bars 32. In such an embodiment, connectors 68 are provided with a head for engaging the underside of the cross-bar 32 in the same manner as the screws 30.

Referring now to Figs. 16-18, the second elongate member comprises a cross-bar 72 of a type modified for use in connection with the embodiment of the spinal stabilizer of the present invention shown in Figs. 14-15. The cross-bar 72 is provided with hooks 74 for engaging the lamina of the vertebra and a retainer 76 which is curved so as to extend under the lamina to which cross-bar 72 is to be affixed. The hooks 74 extend through a slot (not numbered for the sake of clarity) formed at approximately a right angle to the longitudinal axis of cross-bar 72 and are extended in and out of that slot until they are adjusted so as to tightly engage the posterior margin of the lamina and then set in that position by tightening the set screw 78 provided in cross-bar 72 for that purpose. U-shaped connectors 68 mounted on plates 64 as described above are provided for connecting to a rod 22 as shown in Figs. 14-15.

Another embodiment of a spinal stabilizer constructed in accordance with the present invention is shown in Figs. 19-22. In this embodiment, indicated generally at reference numeral 80, both the rods and cross-bars of the spinal stabilizer are formed in the shape of flat, elongate members, and are therefore referred to as first and second elongate members 82 and 84, respectively. First and second elongate members 82 and 84 are attached to each other at an angle of approximately 90° by the interaction of the brackets 86, slots 88, raised ridges 90, gutters 92, guide screws 94, and set screws 96. In more detail, the first and second elongate members 82 and 84 are assembled to each other by placing a second elongate member 84, which functions in the manner of the cross-bar 32 in the embodiments shown in Figs. 1-3 and 12-15, into the "L" 98 of first elongate member 82 and tightening the guide screws 94 and set screw 96 until the screws 94 and 96 engage the margins of the raised ridge 90 and gutter 92 formed on the second elongate member 84. In this manner, the second elongate member 84 is affirmatively connnected to the first elongate member 82, but the second elongate member is movable along its longitudinal axis relative to first elongate member 82. When the surgeon has placed the second elongate

member 84 in the desired location, the set screw 96 is tightened in the gutter 92 to force the back side of second elongate member 84 against the inside of the "L" 98 of first elongate member 82 to retain the second elongate member 84 in that selected position relative to first elongate member 82 and prevent further sliding movement of second elongate member 84 along its longitudinal axis relative to first elongate member 82.

The mounting bracket 86 is then assembled to first elongate member 82 with the set screw 96 riding in the slot 88 of first elongate member 82 and another second elongate member 84 is inserted between the inside surface of the tabs 100 straddling the first elongate member 82 and the underside of the first elongate member 82. Guide screws 94 are then tightened sufficiently to retain the bracket and second elongate member 84 to first elongate member 82 and the second elongate member is slidably adjusted up and down first elongate member 82 to the desired location by the surgeon. Second elongate member 84 is slid back and forth along its longitudinal axis to the desired location relative to the patient's spinal column as described above and the guide and set screws 94, 96 are tightened to affirmatively retain the second elongate member 84 is the selected position relative to first elongate member 82 as described above. Washers of the appropriate shape and size are then selected as required to provide a connection between pedicle screw 34 (not shown) and the spinal stabilizer 80 which provides optimal load transfer between vertebrae and spinal stabilizer. A particular advantage of the embodiment shown in Figs. 19-22 is its low "profile." In other words, when affixed to the vertebrae comprising a patient's spinal column, the dorsal extension of the embodiment shown in Figs. 19-22 is minimized.

In the embodiment shown in Figs. 23-26, the spinal stabilizer, indicated generally at reference numeral 102, is similar to the embodiment shown in Figs. 14 and 15 above in that it is comprised of a first elongate member 104 which is formed in the shape of a rod (or rods as explained below) of the type marketed by MOSS® Miami as described in connection with Figs. 14-15. However, in the embodiment shown in Figs. 23-26, the second elongate member 106 is likewise configured in the shape of a rod. Threaded connectors 108 are provided which are identical in their function to that of the threaded connectors 68 of the embodiment shown in Figs. 14-15, but the connectors 108 include an integral collar 109 in which the second elongate member 106 is journaled so that member 106 is both slidably and rotatably attached to first elongate member 104. In this manner,

after selecting the position of the second elongate member 106 along the length of the first elongate member 104, the second elongate member 106 is slid back and forth along its longitudinal axis 107 to the optimal position and then rotated relative to first elongate member 104 on its longitudinal axis 107 to a position which provides optimal load transfer through the connection between pedicle screw 34 (not shown) and the bearing surface 49 of washer 36 (likewise not shown). The set screw 111 in collar 109 is then tightened to retain the second member 106 in that position. Those skilled in the art who have the benefit of this disclosure will recognize that either of the embodiments shown in Figs. 19-26 could function for their intended purpose with a single first elongate member running substantially parallel to the longitudinal axis of the patient's spine rather than two elongate members located lateral to the dorsal spines of the vertebrae.

Although described in terms of the presently preferred embodiment shown in the figures, those skilled in the art will recognize from this description that changes can be made to the component parts of the present invention without changing the manner in which those component parts function to achieve their intended result. For instance, the present invention is equally adaptable to a spinal fixation system which is comprised of rods on either side of the processes of the vertebrae which may or may not be connected by a cross-bar or a system comprised of a single rod down the dorsal aspect of the spinal column after removal of the dorsal processes rather than the ladder-type system shown in the figures. All such changes, and the others known to those skilled in the art, are intended to fall within the scope of the following non-limiting claims.

WHAT IS CLAIMED IS:

1. A connection between a spinal stabilizer and a pedicle screw for affixing the spinal stabilizer to a vertebral body comprising:

a washer defining means for engaging the spinal stabilizer;

means on the spinal stabilizer for engaging said washer, the engaging means on said washer and the engaging means on the spinal stabilizer cooperating to engage each other at a plurality of points within a common plane with said washer in any one of a plurality of relative rotational positions about an axis substantially perpendicular to said common plane relative to the spinal stabilizer; and

said washer defining a bearing surface and a passage extending through said washer, the pedicle screw extending through the passage and bearing against the bearing surface when the spinal stabilizer is affixed to a vertebral body.

2. The connection of claim 1 wherein the bearing surface of said washer is inclined relative to the common plane.

3. The connection of claim 2 wherein the passage through said washer defines an axis that intersects the common plane, at least one of the angles between the axis and the common plane or the axis and the inclined bearing surface being an acute angle.

4. The connection of any of claims 1-3 wherein said engaging means comprises an aperture in the spinal stabilizer and said washer is provided with cooperating means for engaging said spinal stabilizer adjacent the periphery of the aperture.

5. The connection of claim 4 wherein said engaging means on said washer comprises a shoulder for resting on the spinal stabilizer adjacent the periphery of the aperture, the shoulder and the surface of the spinal stabilizer adjacent the aperture defining the common plane.

6. The spinal stabilizer of claim 1 wherein the passage through said washer defines an axis that interests the common plane, the axis being offset from the center of said washer.

7. A spinal stabilizer comprising:

an elongate member adapted to be affixed to a vertebra and defining a planar aperture;

a washer having engagement means adapted to engage said elongate member adjacent the periphery of the aperture at any one of a plurality of relative rotational positions between said washer and said elongate member about a notional rotational axis which extends through the aperture, said washer having a passage therethrough, one end of the passage communicating with the plane of the aperture and the other end of the passage being located at a bearing surface formed on said washer; and

a screw engaging the bearing surface and extending through the passage and the aperture to engage the vertebra, the axis of the passage intersecting the plane of the aperture at a first angle and the bearing surface at a second angle, at least one of the angles being acute, the plane of the aperture being inclined relative to the bearing surface so that the angle of inclination of the screw extending through the passage is adjusted in dependence upon the relative rotational position between the washer and the elongate member.

8. The spinal stabilizer of claim 7 wherein the axis of the passage intersects the plane of the aperture in said elongate member at a point offset from the notional rotational axis.

9. The spinal stabilizer of claim 7 wherein said elongate member is comprised of a first portion and a second portion, the second portion extending at an angle relative to the first portion.

10. The spinal stabilizer of claim 9 wherein the aperture in said elongate member is located in the second, angled portion of said elongate member.

11. The spinal stabilizer of any of claims 7-10 wherein said engaging means rests on said second elongate member adjacent the periphery of the aperture.

12. The spinal stabilizer of claim 7 additionally comprising a second elongate member slidably attached to said first elongate member for movement relative to said first elongate member.

13. The spinal stabilizer of claim 12 wherein said second elongate member is attached to said first elongate member at approximately a 90° angle.

14. The spinal stabilizer of claim 12 wherein said first elongate member is rotationally movable relative to said second elongate member along the longitudinal axis of said second elongate member.

15. The spinal stabilizer of claim 7 wherein said engagement means comprises a shoulder formed on said washer for engaging surface of said elongate member adjacent the periphery of the aperture.

16. A spinal stabilizer comprising:

a first elongate member;

a screw;

a second elongate member having an aperture therein;

means for attaching said second elongate member to said first elongate member; and

a washer comprising a cylindrical body having one end angled with respect to the side walls of the cylinder and a passage therethrough for receiving said screw and means on said body adapted for engaging the second elongate member at any one of a plurality of rotated orientations relative to said second elongate member.

17. The spinal stabilizer of claim 16 wherein the passage through the body of said washer is offset from the center of the longitudinal axis of the body.

18. The spinal stabilizer of claim 16 wherein the angle of the end of said body is an angle other than 90°.

19. The spinal stabilizer of either of claims 17 or 18 wherein the central axis of the longitudinal passage in said body is not parallel to the longitudinal axis of said body.

20. The spinal stabilizer of any of claims 17-19 wherein said engaging means rests on said second elongate member adjacent the periphery of an aperture defined by said second elongate member.

21. The spinal stabilizer of any of claims 17-19 wherein said second elongate member is slidably attached to said first elongate member for movement relative to said first elongate member.

22. The spinal stabilizer of any of claims 17-19 wherein said second elongate member is attached to said first elongate member at approximately a 90° angle.

23. The spinal stabilizer of claim 16 wherein said second elongate member is slidably attached to said first elongate member for movement relative to said first elongate member.

24. The spinal stabilizer of claim 16 wherein said first elongate member is slidably attached to said second elongate member for movement relative to said second elongate member.

25. A method of affixing a spinal stabilizer comprising a washer, a cross-bar, and a screw to the vertebral body of a patient comprising the steps of:

engaging the cross-bar with the washer;

inserting the screw through an an off-center passage in the washer;

changing the angle of the screw relative to the vertebral body to which the cross-bar is affixed by rotating the washer relative to the cross-bar; and

driving the screw into the vertebral body of the patient to tighten the screw against the washer.

26. The method of claim 25 in which the washer is engaged to the cross-bar by resting the washer on the cross-bar adjacent the periphery of an aperture in the cross-bar.

27. A method of affixing a spinal stabilizer comprising a washer having a cylindrical body with one end angled with respect to the side walls of the cylinder and having a passage therethrough, a cross-bar, and a screw to the vertebral body of a patient comprising the steps of:

engaging the cross-bar with the washer;

inserting the screw through the passage in the washer;

changing the angle of the screw relative to the cross-bar to which the washer is engaged by rotating the washer relative to the cross-bar; and

driving the screw into the vertebral body of the patient to tighten the screw against the washer.

28. The method of claim 27 in which the washer is engaged to the cross-bar by resting the washer on the cross-bar adjacent the periphery of an aperture in the cross-bar.

29. A set of washers for use in connection with an internal spinal stabilizer and a screw comprising:

a first cylindrical body having one end angled with respect to the side walls of the cylinder and defining a passage therethrough, the passage being offset from the center of the longitudinal axis of said first body, for receiving a first screw therethrough;

a second cylindrical body having one end angled with respect to the side walls of the cylinder and defining a passage therethrough for receiving a second screw therethrough; and

means formed on each of said first and second bodies adapted for engaging the spinal stabilizer at any one of a plurality of rotated orientations relative to the spinal stabilizer.

30. The set of washers of claim 29 wherein the end of either said first body or said second cylindrical body, or each of said first and said second cylindrical bodies, is angled at an angle other than 90°.

31. The set of washers of either of claims 28 or 29 wherein the axis of the passage in either said first body or said second body, or each of said first and second bodies, is not parallel to the longitudinal axis of said body.

32. The set of washers of claim 29 wherein said engaging means comprises a shoulder formed on each of said first and second bodies.

33. A washer for use with an internal spinal stabilizer, the washer comprising

a body, the body defining means adapted to engage cooperating engagement means on the stabilizer, the engagement means on the body being adapted to engage the cooperating engagement means on the stabilizer at a plurality of points within a common plane and with the body in any one of a plurality of relative rotational positions about an axis substantially perpendicular to said common plane relative to the stabilizer;

a passage extending through the washer and defining an axis intersecting the common plane at a first predetermined angle at one end of the passage; and

a bearing surface on the body, the axis of the passage intersecting the plane of said bearing surface at a second predetermined angle, at least one of said first or second predetermined angles being an acute angle.

34. A washer for an internal stabilizer having a body defining first engagement means, said engagement means being adapted to engage cooperating engagement means provided on the stabilizer with the washer being rotated to any one of a plurality of positions about an axis substantially perpendicular to a first plane defined by points of contact between said first engagement means and said second engagement means, the washer also defining a bearing surface, the bearing surface being inclined relative to said first plane, there being a passage extending through the washer and defining an axis, the axis of the passage intersecting the first plane at a first predetermined angle and the bearing surface at a second predetermined angle, at least one of the predetermined angles being acute.

35. A washer for use in connection with an internal spinal stabilizer and a screw comprising:

a cylindrical body having one end angled with respect to the side walls of the cylinder;

a passage through said cylindrical body having an opening at the angled end of said cylindrical body, the opening at the angled end of said cylindrical body being offset from the center of the longitudinal axis thereof, for receiving a screw therethrough; and

means formed on said cylindrical body adapted for engaging the spinal stabilizer at any one of a plurality of rotated orientations relative to the spinal stabilizer.

36. The washer of claim 35 wherein the angle of the end of said body is not 90°.

37. The washer of claim 36 wherein the central axis of the passage in said cylindrical body is not parallel to the longitudinal axis thereof.

38. The washer of either of claims 36 or 37 wherein said engaging means comprises a shoulder formed on said cylindrical body.

39. The washer of claim 38 wherein said shoulder extends all the way around the circumference of the side walls of said cylindrical body.

40. A spinal stabilizer for affixing to the vertebral body of a patient comprising:

a first elongate member;

a second elongate member attached to said first elongate member at an angle of approximately 90°, said second elongate member being rotatable about its longitudinal axis relative to said first elongate member; and

a washer, said second elongate member defining means for engaging said washer in any one of a plurality of relative rotational positions at a plurality of points within a common plane about an axis substantially perpendicular to said common plane.

41. A spinal stabilizer for affixing to the vertebral body of a patient comprising:

a first elongate member;

a second elongate member attached to said first elongate member at an angle of approximately 90°, said second elongate member being movable along its longitudinal axis relative to said first elongate member; and

a washer, said second elongate member defining means for engaging said washer in any one of a plurality of relative rotational positions at a plurality of points within a common plane about an axis substantially perpendicular to said common plane.

42. A spinal stabilizer for affixing to the vertebral body of a patient comprising:

a first elongate member;

a second elongate member attached to said first elongate member at an angle of approximately 90°, said second elongate member being movable along the longitudinal axis of said first elongate member; and

a washer, said second elongate member defining means for engaging said washer in any one of a plurality of relative rotational positions at a plurality of points within a common plane about an axis substantially perpendicular to said common plane.

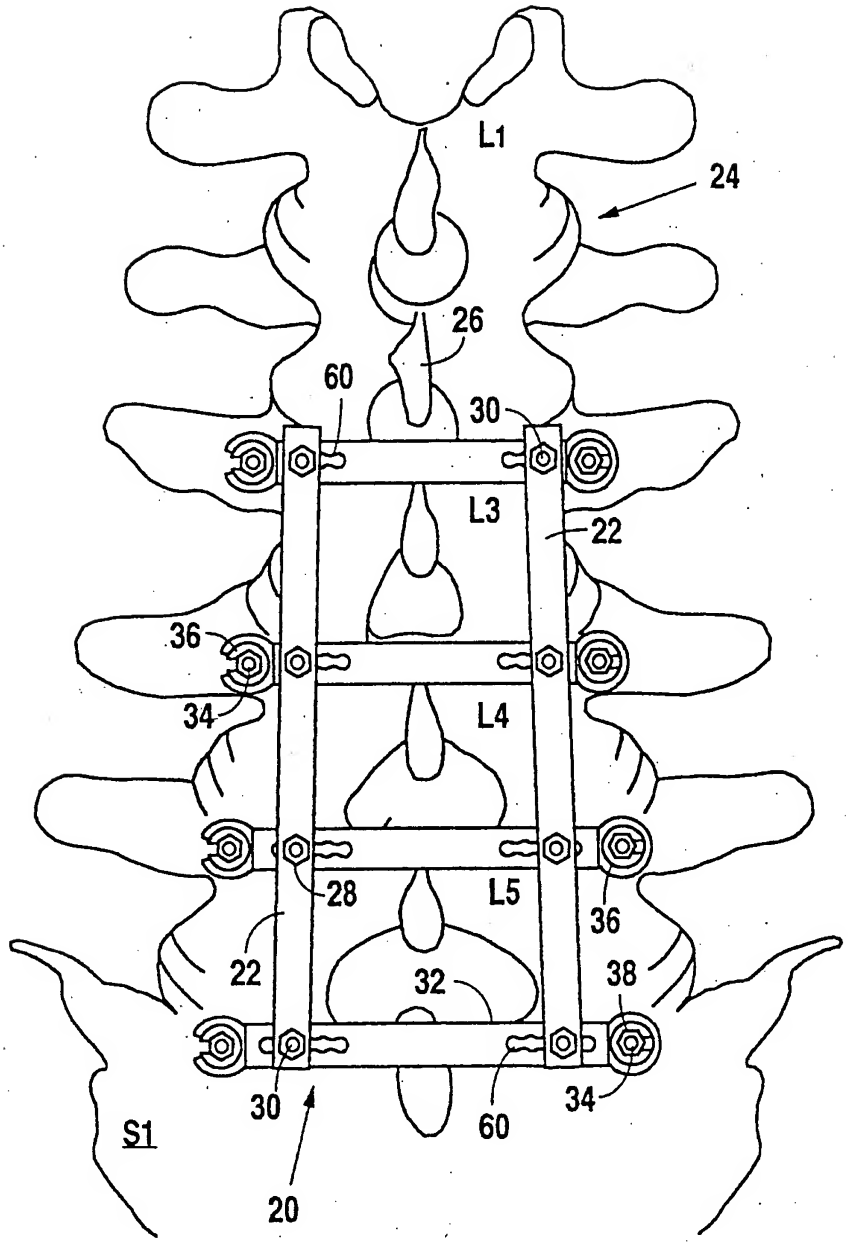


Fig. 1

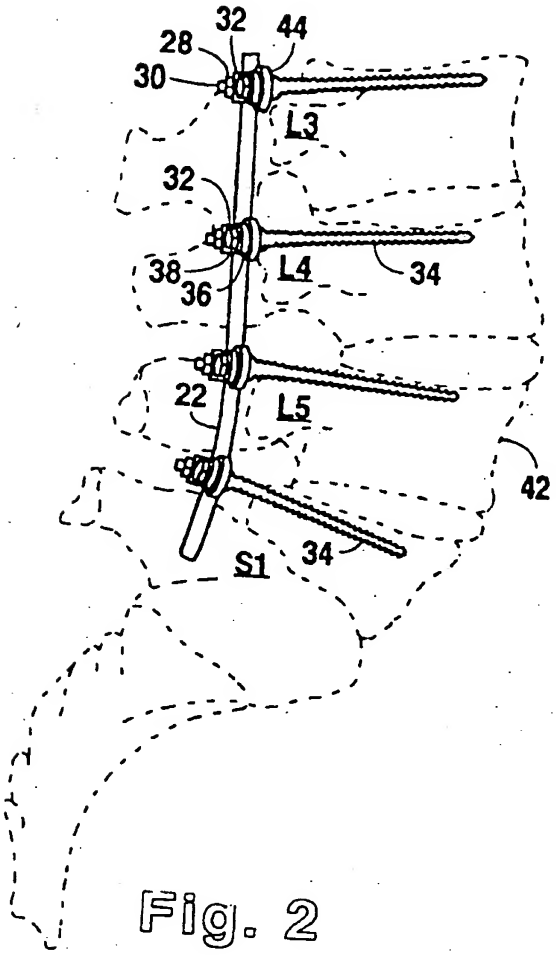


Fig. 2

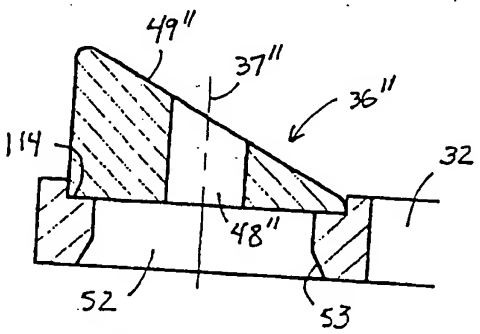


Fig.27

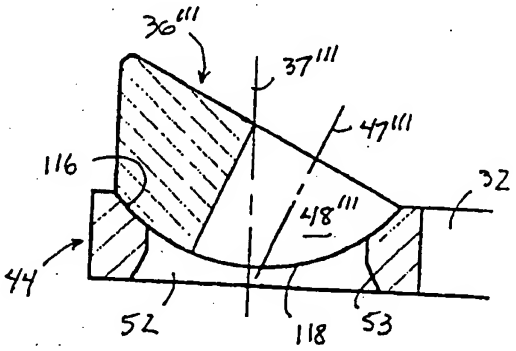


Fig. 28

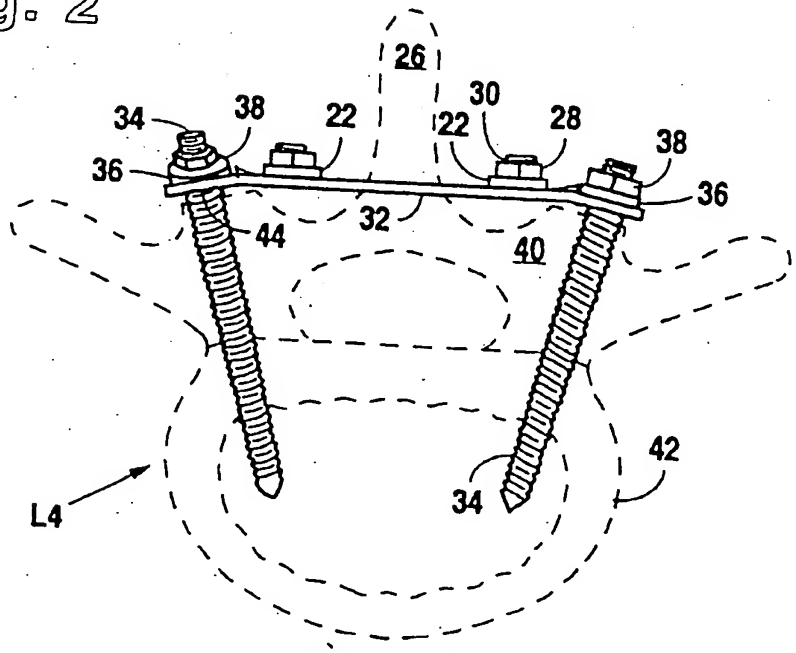


Fig. 3

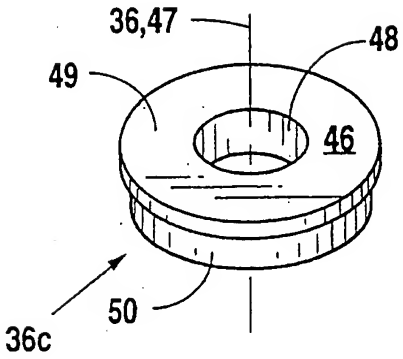


Fig. 4

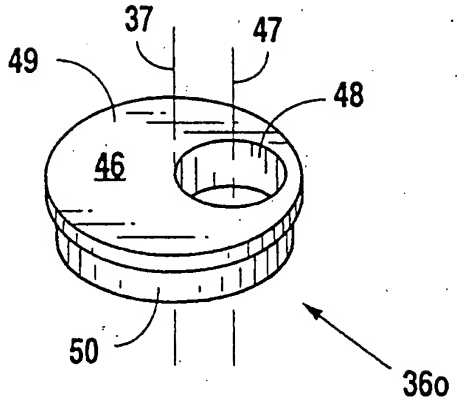


Fig. 5

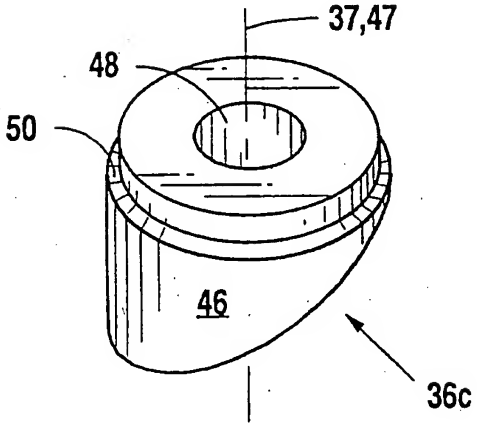


Fig. 6

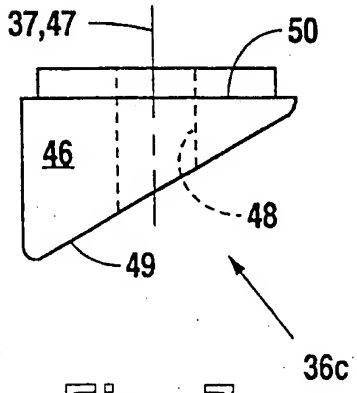
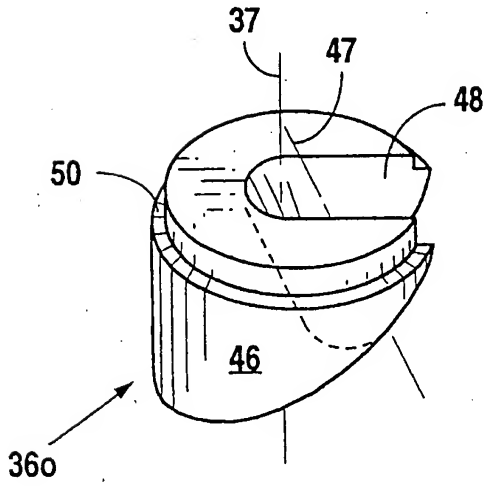


Fig. 7



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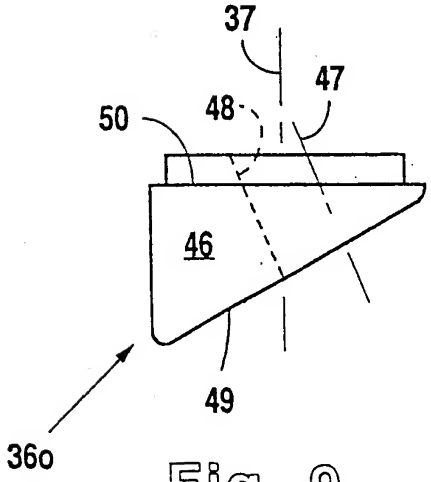

Fig. 9

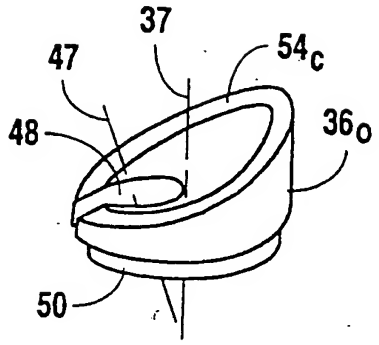

Fig. 10

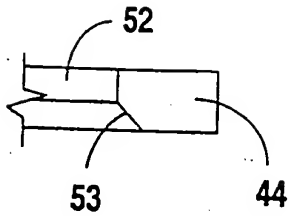

Fig. 13

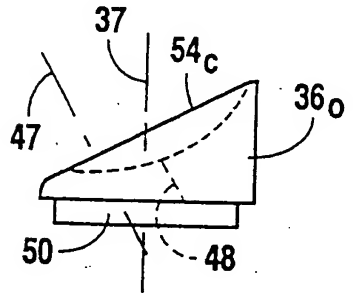

Fig. 11

Fig. 12

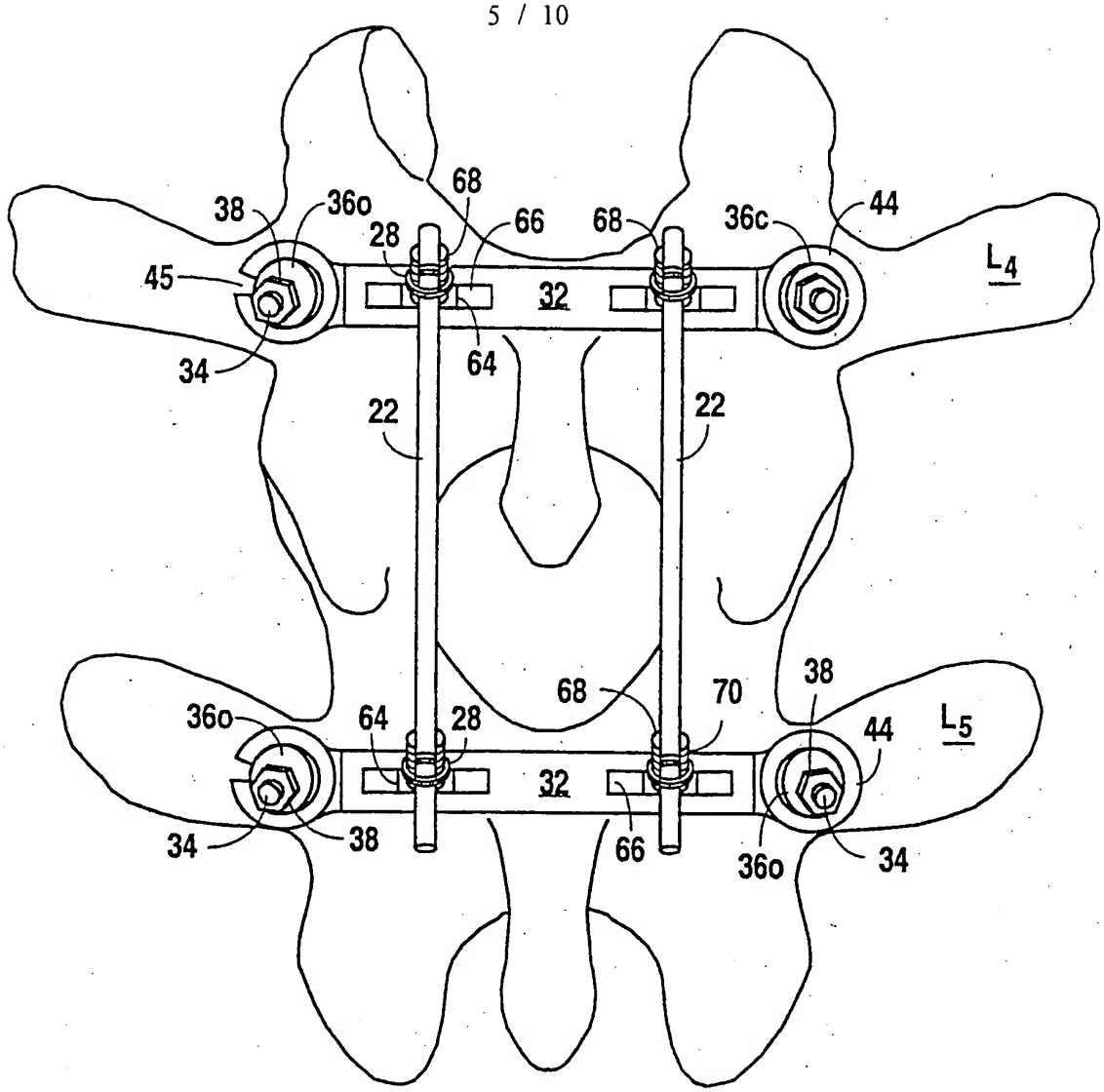
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Fig. 14

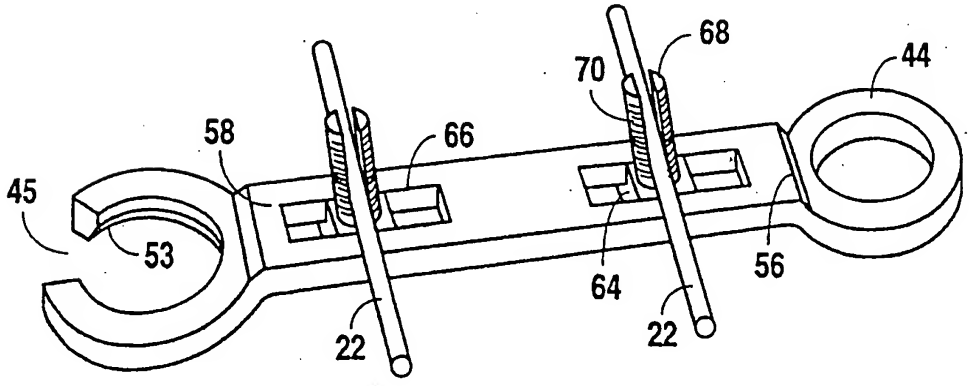
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Fig. 15

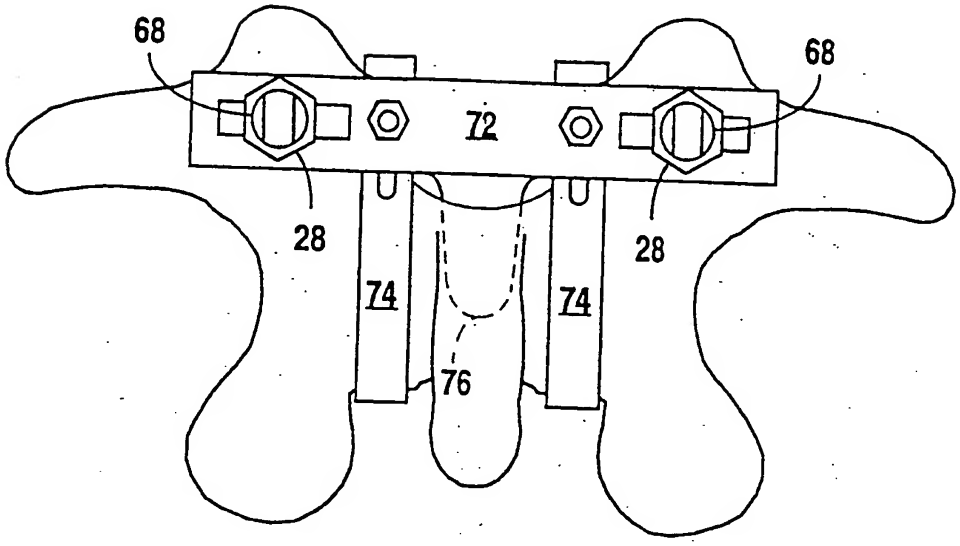

Fig. 16

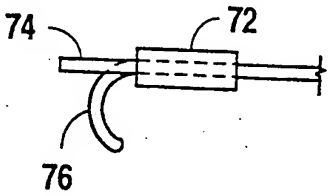

Fig. 18

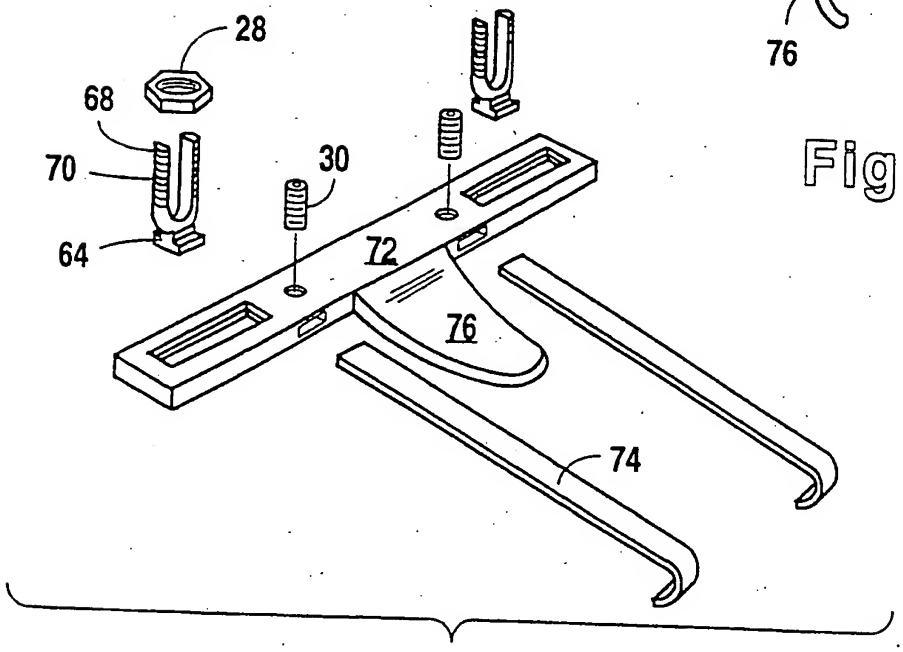

Fig. 17

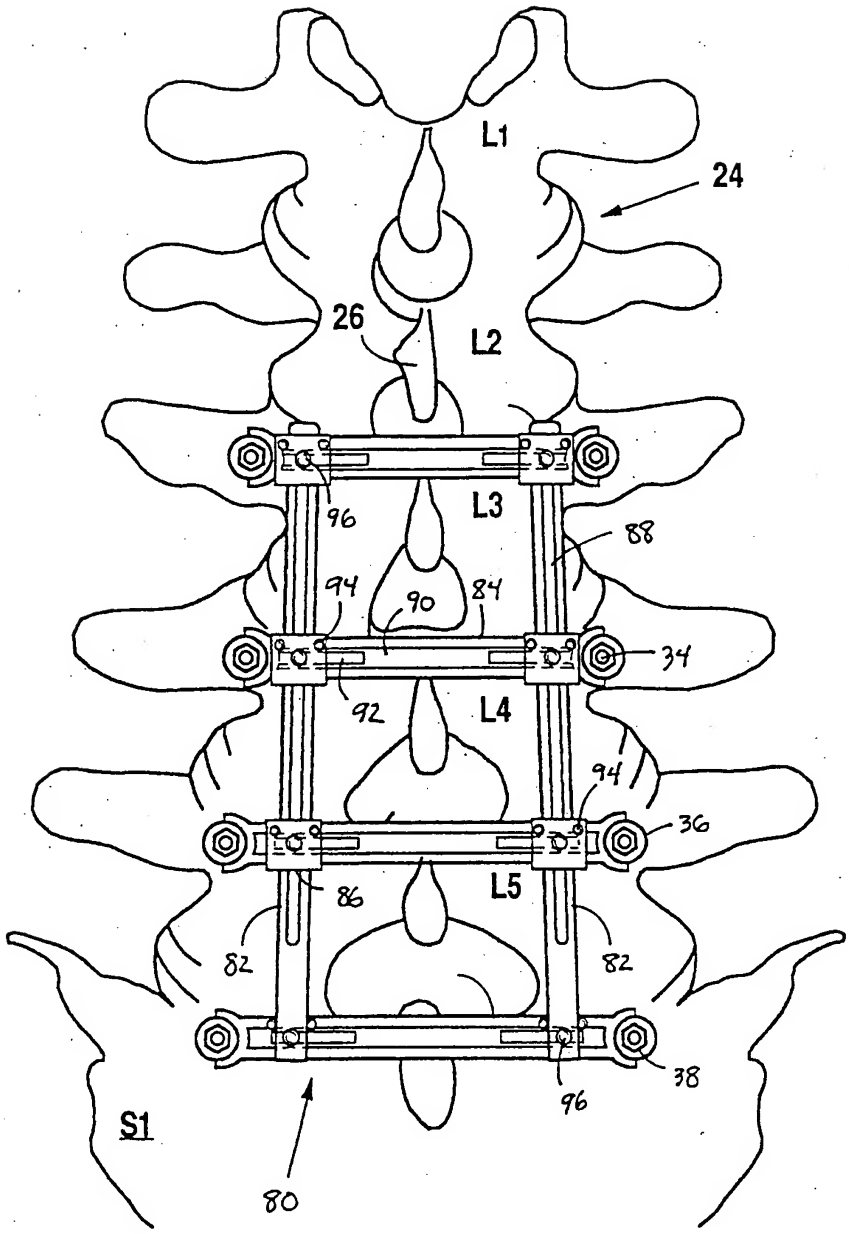

Fig. 19

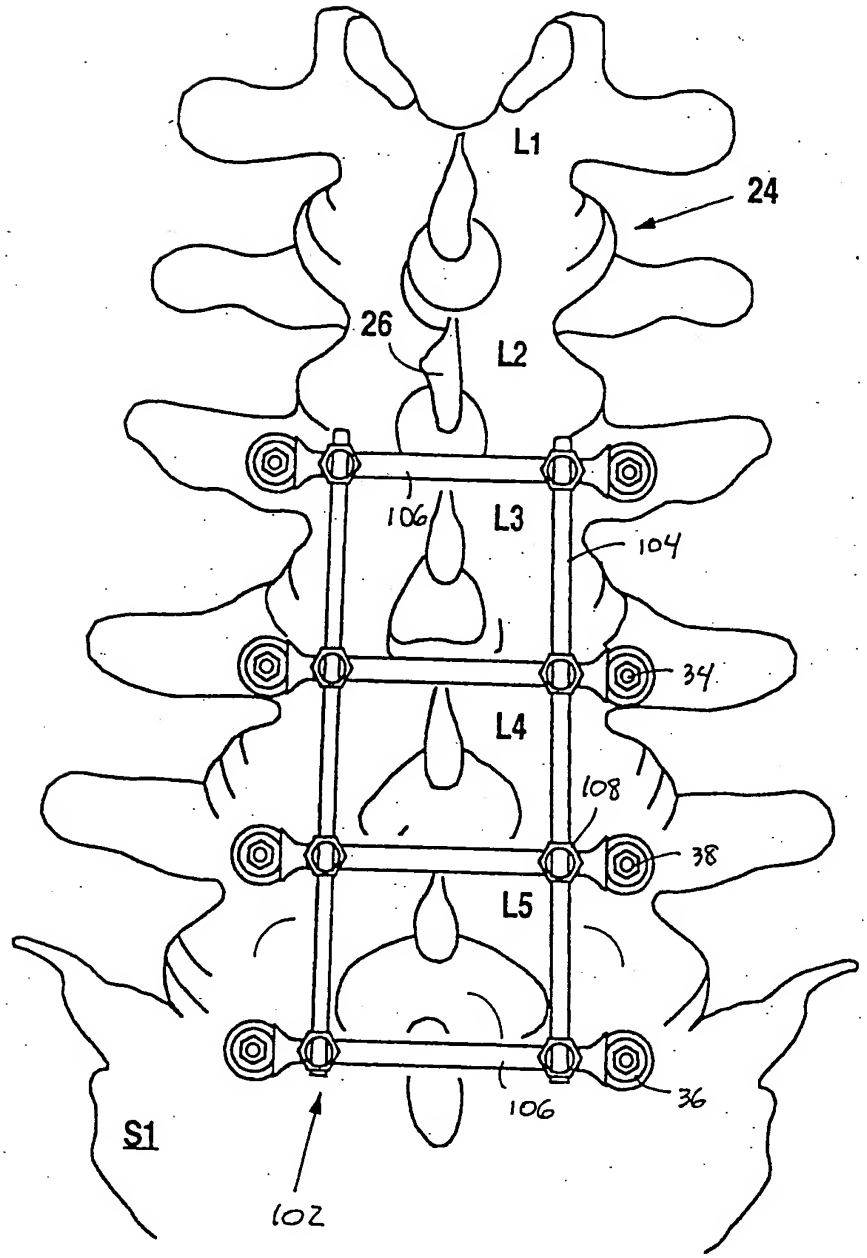

Fig. 23

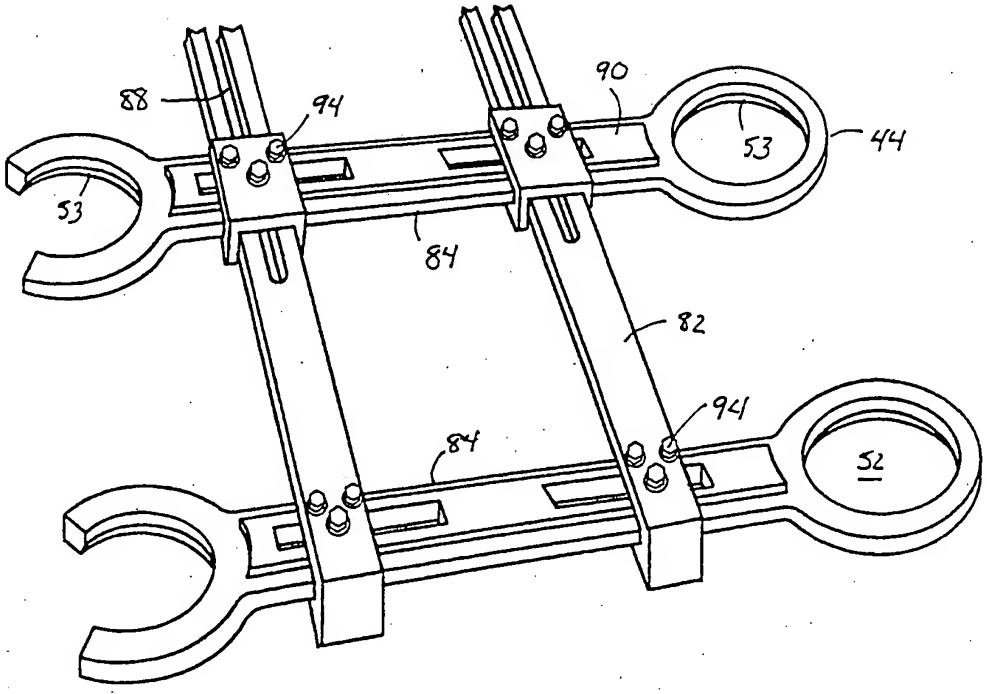

Fig. 20

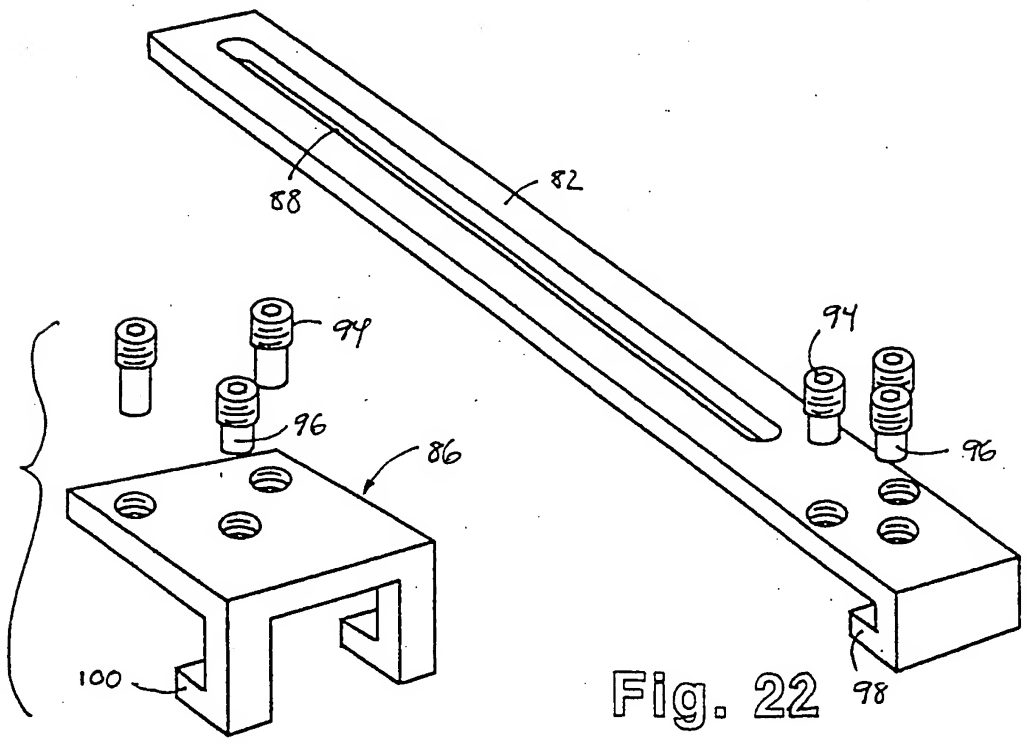

Fig. 22

Fig. 21

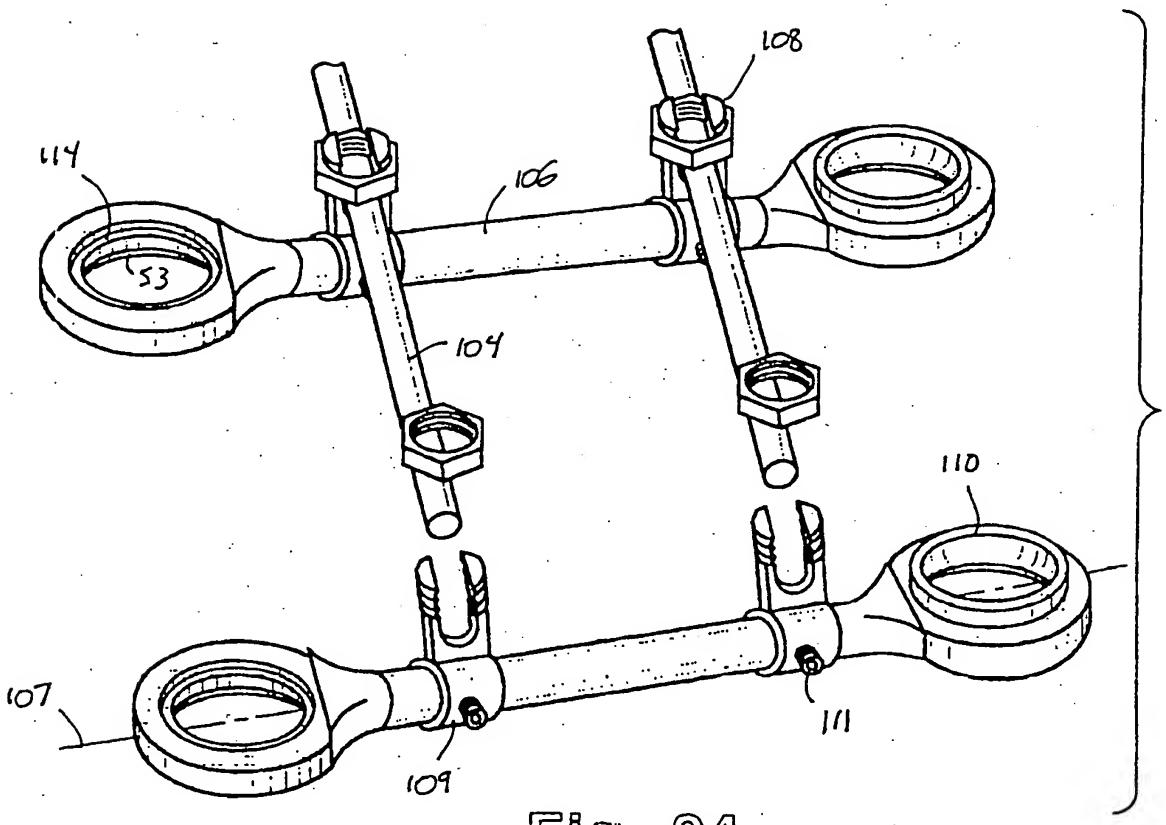

Fig. 24

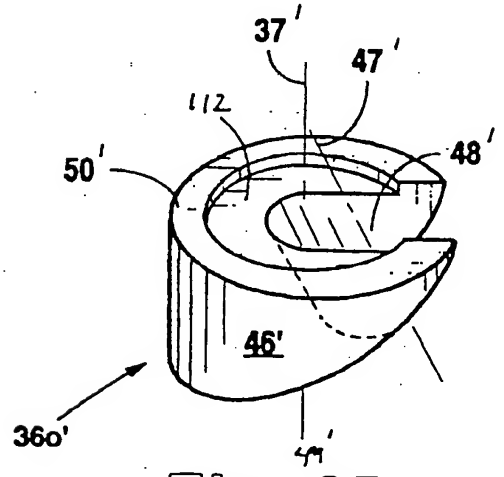

Fig. 25

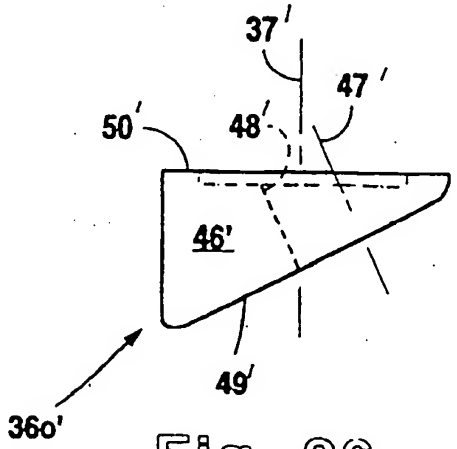

Fig. 26

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 99/22232

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	H.S.AN AND J.M.COTLER (EDS.): "Spinal Instrumentation" 1992 , WILLIAMS & WILKINS , BALTIMORE, US XP002128239 223960 cited in the application page 399 -page 400; figure 24.2 ---	1,4
X	US 5 344 421 A (D.F.CROOK) 6 September 1994 (1994-09-06) column 3, line 19 - line 41; figure 4 ---	1,4
X	FR 2 735 011 A (STE.MECANURGIE) 13 December 1996 (1996-12-13) figure 5 --- -/--	1,4,5

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 January 2000	04/02/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, P

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int I Application No
PCT/US 99/22232

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 846 444 A (BIOMAT) 10 June 1998 (1998-06-10) column 6, line 42 -column 7, line 38 column 8, line 37 - line 43; figures 2,5	1-4,33, 34
X A	FR 2 697 993 A (A.P.ALBY) 20 May 1994 (1994-05-20) page 2, line 4 - line 17; figures 5,10	1,5 29,35
A	FR 2 683 445 A (M.LAHILLE AND J.-P.LEMAIRE) 14 May 1993 (1993-05-14) page 3, line 1 - line 12; figures 1,2	1-4,7, 33,34
A	US 5 092 893 A (T.E.SMITH) 3 March 1992 (1992-03-03) column 3, line 53 - line 57; figure 1	16,40-42
A	US 5 531 747 A (R.C.RAY) 2 July 1996 (1996-07-02) figure 3	16,40-42
A	US 5 743 907 A (M.A.ASHER ET AL.) 28 April 1998 (1998-04-28) figures 8,9	7,33,34

2

INTERNATIONAL SEARCH REPORT

...ne ...onal application No.
PCT/US 99/22232

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 25-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int I Application No
PCT/US 99/22232

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5344421 A	06-09-1994	NONE	
FR 2735011 A	13-12-1996	NONE	
EP 0846444 A	10-06-1998	FR 2756481 A	05-06-1998
FR 2697993 A	20-05-1994	WO 9527444 A	19-10-1995
		AU 6571394 A	30-10-1995
FR 2683445 A	14-05-1993	NONE	
US 5092893 A	03-03-1992	NONE	
US 5531747 A	02-07-1996	US 5531745 A	02-07-1996
		AU 675525 B	06-02-1997
		AU 6404494 A	26-09-1994
		CA 2157678 A	15-09-1994
		CN 1121308 A	24-04-1996
		EP 0688198 A	27-12-1995
		JP 8507458 T	13-08-1996
		US 5470333 A	28-11-1995
		WO 9420048 A	15-09-1996
US 5743907 A	28-04-1998	US 5312404 A	17-05-1994
		US 5129900 A	14-07-1992
		AT 157851 T	15-09-1997
		CA 2046838 A,C	25-01-1992
		CS 9102303 A	15-04-1992
		DE 69127596 D	16-10-1997
		DE 69127596 T	22-01-1998
		EP 0468264 A	29-01-1992
		ES 2107436 T	01-12-1997
		JP 2028671 C	19-03-1996
		JP 6038978 A	15-02-1994
		JP 7063485 B	12-07-1995
		KR 9410075 B	21-10-1994

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(51) International Patent Classification 7 : A61B 17/70

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(11) International Publication Number: WO 00/18312

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(22) International Filing Date: 24 September 1999 (24.09.99)

(30) Priority Data:
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(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 09/161,141 (CIP)
Filed on 25 September 1998 (25.09.98)

(71) Applicant *(for all designated States except US)*: PERUMALA CORPORATION [US/US]; 942 Wild Rose Lane, Brownsville, TX 78520 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: PISHARODI, Madhavan [US/US]; 942 Wild Rose Lane, Brownsville, TX 78520 (US).

(74) Agent: WISNER, Mark, R.; Wisner & Associates, Suite 930, 2925 Briarpark, Houston, TX 77042-3728 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, HR, HU, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

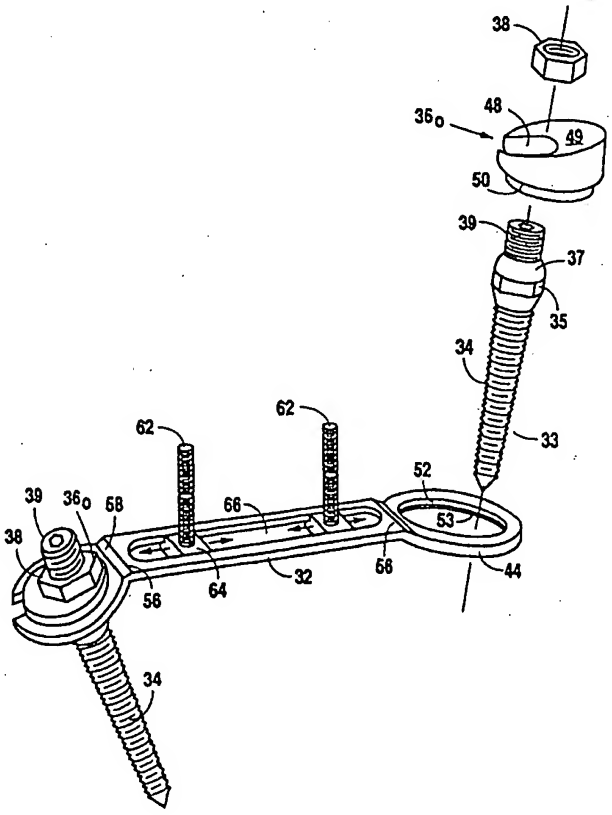
Published
With international search report.
With amended claims and statement.

Date of publication of the amended claims and statement:
2 June 2000 (02.06.00)

(54) Title: MULTI-AXIS CONNECTIONS BETWEEN SPINAL STABILIZERS AND SCREWS

(57) Abstract

A multi-axis correction washer for use with a spinal stabilizer for internal spinal fixation. The bodies of the washer are provided in cylindrical and wedge-shaped cylindrical configurations with a passage in the center of the longitudinal axis of the cylinder and/or offset from the center axis of the cylindrical washer and a shoulder or other structure for rotatably engaging a hole in a spinal implant. The spinal implant can be a plate and screw-type, ladder-type, or monorail-type spinal fixation system. The washer is rotated to provide an infinite range of angles and screw placements relative to the central axis of the spinal column for maximum flexibility of installation and to effectively transfer the load on the spinal column to the implant, all while maintaining an angle of approximately 90° between the head of the screw and/or nut and the washer which engages the implant.



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AMENDED CLAIMS

[received by the International Bureau on 4 April 2000 (04.04.00);
original claims 1-42 replaced by new claims 1-11 (2 pages)]

1. An internal spinal stabilizer comprising:

a first elongate member;

a second elongate member having an aperture therein;

means for attaching said second elongate member to said first elongate member:

a screw for passing through said aperture for affixing said second elongate member to the vertebra of a patient; and

a set of washers, each of said washers being provided with a passage for receiving said screw therethrough and means for engaging said second elongate member adjacent the periphery of the aperture at any one of a plurality of rotational orientations relative to said second elongate member, at least one of the washers of said set of washers comprising a cylindrical body having (a) an end defining a surface against which said screw bears that is inclined relative to the axis of the passage through the washer and (b) the central axis of the passage offset from the center of the body forming the washer, for providing a multiaxial coupling between the vertebra and the second elongate member when rotated relative to said elongate member.

2. The spinal stabilizer of claim 1 wherein the angle of the bearing surface of said washer relative to the axis of the passage through the washer is an acute angle.

3. The spinal stabilizer of claim 1 or 2 wherein at least one washer of said set of washers has a surface against which said screw bears that is angled relative to the axis of the passage through the washer and a passage with a central axis that is coincident with the center axis of the washer.

4. The spinal stabilizer of any of the preceding claims wherein the rotatable engaging means of said washers comprises a shoulder formed on each washer of said set of washers for engaging the surface of said second elongate member adjacent the periphery of the aperture, each said washer being rotatable relative to said second elongate member about a notional rotational axis which extends through the aperture on said shoulder.

5. The spinal stabilizer of any of the preceding claims wherein said second elongate member is attached to said first elongate member at approximately a 90° angle.

6. The spinal stabilizer of claim 1 wherein said second elongate member is slidably attached to said first elongate member for movement relative to said first elongate member.

7. The spinal stabilizer of claim 1 wherein said first elongate member is slidably attached to said second elongate member for movement relative to said second elongate member.

8. A method of affixing a spinal stabilizer comprising a washer, a cross-bar, and a screw to the vertebral body of a patient comprising the steps of:

engaging the cross-bar with the washer;

inserting the screw through an an off-center passage in the washer;

changing the axis of the screw relative to the vertebral body to which the cross-bar is affixed by rotating the washer relative to the cross-bar; and

driving the screw into the vertebral body of the patient to tighten the screw against the washer.

9. The method of claim 8 in which the washer is engaged to the cross-bar by resting the washer on the cross-bar adjacent the periphery of an aperture in the cross-bar.

10. A method of affixing a spinal stabilizer comprising a washer having a cylindrical body with one end inclined with respect to the side walls of the cylinder and having a passage therethrough, a cross-bar, and a screw to the vertebral body of a patient comprising the steps of:

engaging the cross-bar with the washer;

inserting the screw through the passage in the washer;

changing the angle of the screw relative to the cross-bar to which the washer is engaged by rotating the washer relative to the cross-bar; and

driving the screw into the vertebral body of the patient to tighten the screw against the washer.

11. The method of claim 10 in which the washer is engaged to the cross-bar by resting the washer on the cross-bar adjacent the periphery of an aperture in the cross-bar.

STATEMENT UNDER ARTICLE 19

Submitted herewith for filing in the captioned International Application are new claims 1-11, filed under Art. 19 of the Patent Cooperation Treaty. Applicant makes the following under Article 19(1).

Claims 1-24 of the replaced sheets have been replaced by claims 1-7, written to define over the references cited in the International Search Report. Claims 1-7 are based on original claim 16 but have been narrowed by additionally reciting that the invention comprises a set of washers as described in the disclosure. At least one of the washers comprising the claimed set of washers is recited as including an inclined bearing surface and an offset passage for providing a multiaxial coupling between vertebra and spinal stabilizer. New claims 8-11 are identical to claims 25-28 of the application as filed.